

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 10/586,072

Applicant: Brough et al.

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Commissioner for Patents
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DECLARATION UNDER 37 C.F.R. § 1.132 OF DOUGLAS E. BROUGH, PH.D.

1. I, Douglas E. Brough, am Executive Director of Vector Sciences at GenVec, Inc. and the inventor of the subject patent application.
2. The following experiments were performed at my direction.
3. The efficiency of adenoviral vector-mediated gene delivery and expression in inner ear tissues was tested in a utricle culture model. Specifically, gene expression from adenoviral vectors based on serotype 35 (Ad35) and serotype 28 (Ad28), which are of subgroup B and D, respectively, was compared to gene expression from an adenoviral vector based on serotype 5 (Ad5), which is of subgroup C. Utricle tissue was dissected from adult CBA mice, and cultures were established (see, e.g., Staecker et al., *Otol. Neurotol.*, 28(2): 223-231 (2007)). E1-deleted adenovirus vectors expressing the green fluorescent protein (GFP) from the CMV promoter were prepared using Ad35, Ad28, and Ad5 serotypes. The utricle cultures were infected with the resulting adenoviral vectors, and GFP expression was evaluated.
4. The results of the above-described experiment suggested that the Ad28 and Ad35 vectors exhibited enhanced delivery to the utricle cultures, as compared to the Ad5 vector. In order to determine if binding and entry of the Ad28 vector to utricle tissue was

increased as compared to the Ad5 vector, quantitative PCR (qPCR) was used to quantify the amount of adenovirus vector genome present after infection of utricule cultures. The results of this experiment demonstrate that the Ad28 vector exhibits enhanced delivery to utricule tissue as compared to the Ad5 vector.

5. I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date

24 Feb 2009


Douglas E. Brough, Ph.D.